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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,484	02/17/2004	David B. Rozema	Mirus.030.16.04	2135

7590 08/04/2005

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,484	ROZEMA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 7-8, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Heiliger et al. (US 5,453,461).

Heiliger et al discloses biologically active polymers that are covalently attached to a biologically active segment, wherein the biologically active segment is an oligonucleotide that comprises 1 to 80, 15 to 50, or 20 to 35 nucleotide units in length, see col. 1, lines 54-67, having the formula: P-(A)q, wherein the P polymer component may be linear, branched, or cross-linked, and wherein the monomer units for the polymer components are acrylic, methacrylic, vinyl, or styryl derivatives, wherein the derivatives may be, for example, their acid, ester, amide or ketone derivatives. (A) represents a biologically active section and q is the number 1 o r 2 (see col. 2, lines 1-67). The polymers of Heiliger et al. preferably have a molecular weight of between 1,000 and 10,000,000 (see col. 3, lines 20-38).

3. Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al. (US 5,218,105).

Cook et al. discloses oligonucleotide analogs that are modified by the covalent attachment of polyamines at the 5' terminal nucleotide (see col. 5, lines 1-68). The oligonucleotides of the invention include antisense oligonucleotide (col. 5, line 4). The compositions of Cook et al. are disclosed as functioning to enhance the cellular uptake of antisense oligonucleotides into cells (see col. 4, lines 5-10).

4. Claims 1-8, 16 and 19-20 are rejected under 35 U.S.C. 102(e or a) as being anticipated by Pinchuk et al. (US 2002/0107330).

Pinchuck et al. teach compositions for delivery of a therapeutic agent, wherein said compositions comprise a biocompatible block polymer of copolymer of one or more of the following: polycarboxylic acid, a cellulose acetate polymer, a cellulose nitrate polymer, a gelatin, a polyvinylpyrrolidone, a cross-linked polyvinylpyrrolidone, a polyanhydride, a polyamide, a polyvinyl alcohol, a polyvinyl ether, a polyvinyl aromatic, a polyethylene oxide, a glycosaminoglycan, a polysaccharide, a polyester, a polyacrylamide, a polyether, a polyether sulfone, a polycarbonate, a polyalkylene, a halogenated polyalkylene, a polyurethane, a polyorthoester, a polypeptide, a silicone, a siloxane polymer, a polylactic acid, a polyglycolic acid, a polycaprolactone, a polyhydroxybutyrate valerate, a fibrin, a collagen, a collagen derivative or a hyaluronic acid. Particularly preferred polymers and copolymers are polyacrylic acids, ethylene-vinyl acetate copolymers, and copolymers of polylactic acid and polycaprolactone (see page 1, [0016]).

The Pinchuck et al. invention relates to compositions comprising a therapeutic-agent-loaded block copolymer that are useful for delivery of a therapeutic agent and to biocompatible block copolymer materials useful, for example, in connection with intravascular or intervascular

medical devices [0026]. The compositions of Pinchuck et al. are also designed wherein the therapeutic agent is covalently bonded to the block copolymer matrix (see [0198]). Exemplary genetic therapeutic agents include antisense DNA and RNA [0077-0078].

5. Claims 1, 7-8, 17-18 and 19 are rejected under 35 USC 102(b) as being anticipated by Anderson et al. (US 5,169,933).

Anderson et al. teach a covalently-linked complex for targeting a defined population of cells, comprising: a targeting protein; a cytotoxic agent; and an enhancing moiety, wherein the enhancing moiety promotes covalently-linked complex target cell interaction. In a specific embodiment, the covalently-linked complex comprises wherein the enhancing moiety is a translocating/internalizing moiety, and further wherein said moiety is a pardaxin. It is further contemplated that the enhancing moiety is covalently linked to the targeting protein of the cytotoxic agent through a peptide spacer having 1-40 amino acids (see col. 28, lines 28-31).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 9-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-10, 15-19 and 28-29 of

copending Application No. 10/772,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application broadly encompass the full scope of the invention recited in the claims of the copending patent application, wherein the claims of the copending application represent a species of the broad genus of compositions recited in the instant claims. As such the claims of the copending application are considered to essentially anticipate the claims of the instant application. For example, the claims of the instant application are drawn to a composition comprising a membrane active polyamine-biologically active compound conjugate, wherein the polymer is linked to the biologically active compound via a labile covalent bond and the amines on the polymer are reversibly modified, however the claims of the copending application (and instant claim 16) are limited to wherein the polyamine consists of a polyvinyl ether. Claim 28 of the copending application recites that the modification on the polyvinylether consists of a reversible modification. Moreover, the specification as filed discloses that reversibly modified polyvinylether polymers covalently attached to a polynucleotide is a preferred alternative embodiment, see paragraph [0017]. Therefore, the instantly claimed invention is considered an obvious alternative embodiment of the claims recited in the copending patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1633

JLE